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Food Safety And Inspection Service
Technical Service Center
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AUDIT REPORT FOR ISRAEL

May 4 through May 17, 2000

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Israel's poultry inspection system from May 4 through May 17, 2000. Eight of the sixteen establishments certified to export poultry to the United States were audited. Five of these were slaughter establishments; the other three were conducting processing operations.

The last audit of the Israeli poultry inspection system was conducted in January 1999. Fourteen establishments were audited. Establishments 3, 9, 11, 14, 18, 19, 22, 52, 101, 104, 108, 109, 118, and 119 were acceptable. No serious deficiencies were reported at that time. HACCP-implementation was deficient in one of the fourteen establishments visited Est. 14). During this new audit, Establishment 14 was included in the new itinerary for records review. The major concerns from the previous audit were the following:

1. Exposed edible products were not handled in a sanitary manner in Establishments 3, and 9. *During this audit, this deficiency was found to have been corrected.*

2. Gaps at the sides of doors and a few openings through the walls to the outside were not sealed properly to prevent the entrance of rodents and other vermin in the dry storage, shipping, and receiving rooms in Establishments 9, 11, 18, and 119. No evidence of rodents or other vermin was observed at the time of the review. *The documents indicated that this had been corrected except in Establishment 9.*

3. The laboratory quality assurance program needed improvement. *The laboratory quality assurance program was improved but still needed more improvements.*

4. The species verification program was not carried out as required by FSIS. *Species verification testing is carried out on cooked poultry products intended for export to the U. S. as referred to Dr. E. Nili's letter dated March 6, 2000. This was verified during this on-site audit.*

5. The HACCP program was not implemented in Establishment 14. *The documents indicated that this deficiency had been rectified.*

The major concerns from the new audit were the following:

1. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed. Neither establishment personnel nor GOI inspection officials were performing adequate ongoing verification activities of the HACCP program.

2. The zero-tolerance policy for visible fecal material on carcass was not enforced by the GOI inspection officials and establishment personnel, and no monitoring record was maintained to verify this activity in Establishments 3, 5, 9, 11, 14, 18, and 19.

3. Both establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of all documentation pertaining to the monitoring of critical limits and, if appropriate, documentation, that corrective actions were taken, including the proper disposition of the product, for each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail. GOI meat inspection officials indicated they would implement this requirement promptly.

4. The intralaboratory check samples program was not adequately maintained. No check samples for chlorinated hydrocarbons and organophosphates were carried out in March or April 2000, and no check samples at all were being done for hormones, trace elements, chloramphenicol, sulfonamides, or antibiotics as required. This is a repeat deficiency from last audit.

Israel exports only poultry processed products to the United States. Restrictions are placed on Israeli fresh poultry due to presence of Newcastle disease. Meat products are ineligible because USDA does not recognize Israel's meat inspection system as equivalent.

During the period of January 1, 2000, to March 31, Israeli establishments exported 936,243 pounds of processed turkey and chicken to the U.S. Port-of-entry rejections were for net weight violations (1.46% of the total), missing shipping marks (0.02%).

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Israeli national poultry inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the poultry inspection headquarters facilities preceding the on-site visits. Establishments 3, 5, 9, 19, 52, 104, 108, and 186 were selected randomly for on-site-audits and Establishments 11, 14, 18, 22, 101, 118, and 119 were selected for records reviews. The third was conducted by on-site visits to establishments. The fourth was a visit to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for the presence of microbiological contamination with *Salmonella*.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species. Israel's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials. This was the case with Establishment 5 (see below).

RESULTS AND DISCUSSION

Summary

Eight establishments, Ests. 3,5,9,19,52,104, 108, and186 were audited; two establishments, Ests. 3 and 19 were recommended for re-review. One establishment, Est. 5, was found to be unacceptable. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli* are discussed later in this report.

As stated above, major concerns had been identified during the last audit of the Israeli poultry inspection system, conducted in January 1999. During this new audit, the auditor determined that most major concerns had been addressed and corrected.

During this new audit, a few deficiencies were found in the implementation of the required HACCP programs in fifteen establishments (eight for on-site audits and seven for records audits) visited. Details are provided in the Slaughter/ Processing Controls section later in this report.

Entrance Meeting

On May 4, an entrance meeting was held in Tel Aviv with Dr. Oded Nir (Markusfeld), Director of Veterinary Services and Animal Health (VSAH); Dr. Isaac Klinger, Deputy Director of Veterinary Services and Animal Health; Dr. Eliezer Nili, Director, Control of Animal Products; Dr. Michael Hirik, Area Supervisor, Southern District; Dr. Karol Vigvari, Area Supervisor, Northern District; and Dr. Roint Davidovitch, HACCP Project Manager and Dr. Faizur Choudry, International Audit Staff Officer. Topics of discussion included the following:

1. Updates on the inspection system of Israel
2. The audit itinerary and travel arrangements
3. Delistment issues
4. Generic *E. coli* and *Salmonella* and *Listeria* testing and species verification program.
5. HACCP implementation
6. SSOP implementation

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Israel's inspection system in January 1999.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of inspection system documents pertaining to the establishments listed for records review. This records review was conducted at the Ministry of Agriculture and Rural Development in Tel Aviv and in establishments. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel.
- Label approval records such as generic labels.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

The following concerns arose as a result the examination of these documents.

1. The HACCP plan did not specify critical limits, monitoring procedures and monitoring frequencies performed for each CCP adequately.

2. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed. Neither establishment personnel nor GOI inspection officials were performing adequate ongoing verification activities of the HACCP program.

3. Corrective actions to be followed in response to a deviation from a critical limit not addressed in the written HACCP plan.

4. The zero-tolerance policy for visible fecal material on carcass was not enforced by the GOI inspection officials and establishment personnel, and no monitoring record was maintained to verify this activity in Establishments 3, 5, 9, 11, 14, 18, and 19.

5. Both establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of all documentation pertaining to the monitoring of critical limits and, if appropriate, documentation that corrective actions were taken, including the proper disposition of the product, for each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail; GOI meat inspection officials indicated to implement this requirement promptly.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Israel as eligible to export poultry products to the United States were full-time government employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Sixteen establishments were certified to export poultry products to the United States at the time this audit was conducted. Eight establishments, Est. 3,5,9, 19,52, 104, 108, and 186 were visited for on-site audits.

With the exception of Establishment 5, corrective actions were prompt and effective.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved, and private laboratories.
2. Intra-laboratory quality assurance procedures, including sample handling.
3. Methodology.

The Kimron Veterinary Institute, National Residue Control Laboratory in Beit Dagan was audited on May 17, 2000. The Institute for Food Microbiology and Consumer Goods in Tirat Carmel was audited on May 14, 2000. Except as noted below, effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, and percent recovery. The methods used for the analyses were acceptable. No compositing of samples was done.

The check sample program was not adequately maintained such as, the intralaboratory check samples for chlorinated hydrocarbons and organophosphates were not carried out in March and April in 2000, and for hormones, trace elements, chloramphenicol, sulfonamides and antibiotics were not carried out as required by FSIS. Polychlorinated biphenyls (PCB's) were not analyzed as required by FSIS. Dr. Eliezer Nili, indicated that with respect to residue control program, he complied with Mr. Mark Manis, Director, International Policy Division, Office of Policy, Program Development and Evaluation, FSIS, letter dated December 31, 1997, which stated that each country determine which compounds should be included in its annual residue sampling plan and he decided not to. The following information was not recorded in the official record books for Laboratory Quality Assurance Program.

1. Lot numbers, expiration dates and where the standard solutions/reagents/media ingredients were purchased, were not recorded in the standards books.

2. The record books were not signed and verified by the supervisors each time before the newly prepared solutions were used by the technicians or chemists.

3. No record was maintained for the corrective actions taken when unacceptable check sample results were received.

Israel's microbiological testing for *Salmonella* was being performed in private laboratories. One of these, the Institute for Food Microbiology and Consumer Goods laboratory in Tirat Carmel was audited on May 14, 2000, and found acceptable. The auditor determined that the system met the criteria established for the use of private laboratories under FSIS's Pathogen Reduction/HACCP rule. These criteria are:

1. The laboratories were accredited/approved by the government, accredited by third party accrediting organization with oversight by the government, or a government contract laboratory.

2. The laboratories had properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.

3. Results of analyses were being reported to the government or simultaneously to the government and establishment.

Establishment Operations by Establishment Number

The following operations were being conducted in the eight establishments:

Kosher - chicken slaughter and cut-up – two establishments (5 and 9)
Kosher- turkey slaughter and cut-up – two establishments (3 and 19)
Fried chicken patties – one establishment (186)
Cooked Sausages, cured and smoked products – one establishment (52, 104, and 108)

SANITATION CONTROLS

Based on the on-site audits of establishments, Israel's inspection system had controls in place for water potability records; chlorination procedures; back-siphonage prevention; hand washing facilities; sanitizers; separation of operations; pest control and monitoring; temperature control; lighting; work space; ventilation; maintenance and cleaning of over-product ceilings and equipment; dry storage areas; personal dress, habits, and hygiene; equipment sanitizing; product handling, storage, and transpotation; antemortem facilities; welfare facilities; and outside premises.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements. The following deficiencies were noted.

Cross-Contamination

1. Turkey carcasses were found with grease and rail dust and were not effectively trimmed for defects at the pre-boning trim station in Establishment 3.

2. Several turkey carcasses were found with grease contamination and were not effectively trimmed for defects at the pre-boning station in Establishment 19.

3. Turkey carcasses were contacting the work platform and employees' boots at the turkey transfer station in the cut-up room. Edible product was contacting contaminated racks through the perforated bottoms of plastic containers in the boning room and coolers in Establishment 3.

4. Water was leaking from an overhead pipe onto a chicken rack at the hock cutter station. A carton conveyor passing over exposed product areas was not protected to prevent any fallout onto the product underneath in the cut-up and packaging rooms in Est. 5.

5. Cleaned edible product containers were passing through dirty plastic strip curtains from the container washing room to the boning room in Establishment 9.

6. Turkey carcasses were contacting a contaminated hose at the eviscerating line. A cleaning rod for the turkey thoracic cavity was contacting the contaminated trough during rinsing prior to reuse in the slaughter room in Establishment 19.

7. Establishment employee was not washing his hands before handling edible product after using dirty equipment to open grinding machine in Establishment 52.

8. Dripping condensate from overhead refrigeration units, ducts, and ceilings that were not cleaned/sanitized daily was falling onto exposed edible product, and packaged boxes of meat in the cooler, cut-up room, packaging room, shipping room, and slaughter room in Establishment 5.

9. Dripping condensate from overhead refrigeration units and ceilings that were not cleaned/sanitized daily was falling onto packaged meat boxes and edible product containers covered with plastic in the defrosting and packaging room in Est. 52.

10. Dripping condensate from ceilings that were not cleaned/sanitized daily was falling on exposed product in the boning room in Establishment 9.

11. Dripping water from a rusty ice machine frame that was not cleaned/sanitized daily was falling into the ice container in the ice room in Establishment 52.

<u>Basic Establishment Facilities</u>

1. A sanitizer was not maintained at the required temperature in the chicken cut-up room in Establishment 5.

2. Neither establishment personnel nor GOI inspection officials had adequate knowledge of or control over the use of insecticides and rodenticides by the contracted pesticide company “Lenglive Eitan Sanitation and Pesticide Control, Limited". Gaps at the bottom and sides of door, openings to the outside at the junction of walls and ceilings were not sealed properly in the shipping room and the entrance to employees’ locker room to prevent the entrance of rodents and other vermin in Establishment 5.

3. There was no door to separate the slaughter room from the product receiving and water pump room to prevent the entrance of rodents and other vermin in Establishment 9.

4. Gaps at the bottoms of door in the product shipping room were not sealed properly to prevent the entrance of rodents and other vermin in Establishment 19.

Condition of Facilities Equipment

1. Condensate from ceilings that were not cleaned/sanitized daily was dripping in the chicken cut-up room and cooler in Establishment 19. No product was underneath at the time of the audit.

2. Dripping condensate from overhead refrigeration units, and ceilings that were not cleaned/sanitized daily, was falling onto packaged meat product in two coolers in Establishment 104.

3. A product wrapping machine that was ready for use but not in use, in the packaging room was observed with dried fat, meat and flaking paint and seams at the junctions of boning tables and stands and also numerous edible product containers were not sealed completely in the boning room in Establishment 3.

4. In the product packaging and mechanical deboning room, conveyor belts were found with grease and deep cuts, and were extensively deteriorated, racks used for un-packaged and packaged product were observed with dried fat, meat, and extraneous material in Establishment 5.

5. Overhead beams and supports between the freezer and shipping rooms, ceilings in the mechanical deboning room, and electrical cables in the cut-up and packaging rooms were observed with accumulations of dust, dirt, extraneous material, and flaking paint in Establishment 5.

6. All chutes for edible product between cut-up and packaging rooms did not have smooth surfaces and were cracked; packaging material was stored underneath steps and was not protected to prevent any fallout; a build-up of dust and debris was observed at the entrance to the carton conveyor chutes in the dry storage room in Establishment 5.

7. Processed product packaging machines were too close to an open drain with running water, with a potential for splash contamination from drain water in the processing room in Establishment 104.

8. A buildup of dust, debris and feathers was observed on the floor, and covings on the walls and floor junctions were not sealed properly to prevent the entrance of rodents and other vermin in the dry storage room in Establishment 3.

9. A buildup of dust and debris was observed on the floor and some packaging materials were stored on the floor and gaps at the bottom of door were not protected to prevent the entrance of rodents and other vermin in the dry storage

9. The daily pre-operational and operational SSOPs records did not reflect the actual sanitary conditions observed in Establishment 5.

ANIMAL DISEASE CONTROLS

With the exception listed below, Israel's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, humane handling and slaughter, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

1. Edible and inedible product containers were not identified in the boning and slaughter rooms in Establishments 3, 5, and 9.
2. Edible and inedible product containers were not identified in the processing room in Establishment 108.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

There were adequate animal identification and traceback, humane handling and slaughter of animals and control of condemned products.

RESIDUE CONTROLS

Israel's National Residue Testing Plan for 1999 was being followed, and was on schedule. Except as noted below, the Israel's inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.
(Please see laboratory audit section)

SLAUGHTER/PROCESSING CONTROLS

Israel's inspection system had controls in place to ensure adequate animal identification; antemortem inspection procedures; antemortem disposition, humane slaughter; postmortem inspection procedures; postmortem dispositions; condemned product control; restricted product control; ingredients identification; control of restricted ingredients; formulations; processing schedules, equipment and records, and processing controls of cured, dried, smoked products and cooked sausages.

HACCP Implementation

All establishments approved to export poultry products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were audited and found to meet the basic FSIS regulatory requirements, with the following variations:

1. The HACCP plan did not specify critical limits, monitoring procedures and monitoring frequencies performed for each CCP adequately.

2. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed. Neither establishment personnel nor GOI inspection officials were performing adequate ongoing verification activities of the HACCP program.

3. Corrective actions to be followed in response to a deviation from a critical limit not addressed in the written HACCP plan.

4. The zero-tolerance policy for visible fecal material on carcass was not enforced by the GOI inspection officials and establishment personnel, and no monitoring record was maintained to verify this activity in Establishments 3, 5, 9, 11, 14, 18, and 19.

5. Both establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of all documentation pertaining to the monitoring of critical limits and, if appropriate, documentation that corrective actions were taken, including the proper disposition of the product, for each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail; GOI meat inspection officials indicated to implement this requirement promptly.

Testing for Generic *E. coli.*

Israel has adopted the FSIS regulatory requirements for *E. coli* testing. Seven of the eight establishments audited were required to meet the basic FSIS regulatory requirements for generic *E.coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing program was audited and found to meet the basic FSIS regulatory requirements.

Additionally, establishments had adequate controls in place to prevent poultry products intended for Israeli domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

Except as noted below, and with the exception of the unacceptable establishment (Est. 5), the GOI inspection system controls [ante-and post-mortem inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, importation of only eligible poultry products from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible poultry products from other countries for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

All of the eight establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Israel has adopted the FSIS regulatory requirements for *Salmonella* testing.

The *Salmonella* testing programs were found to meet the basic FSIS regulatory requirements.

Listeria monocytogenes

1. The control of *Listeria monocytogenes* is not included in the HACCP plan in Establishments 22, 52, 101, 104, 108, 118, 119, and 186.

2. GOI inspection service has a surveillance program for *Listeria monocytogenes* testing (one sample from each shipment intended for export to the U. S.).

Species Verification Testing

At the time of this audit, Israel was not exempt from the species verification testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements (criteria for sampling: less than 500 kilos one sample, 500 kilos to 5 tons 3 samples, and more than 5 tons 6 samples).

Monthly Reviews

These reviews were being performed by Dr. Karol Vigvari, Area Supervisor, Northern District, and Dr. Michael Hirik, Area Supervisor, Southern District.

The internal review program was applied equally to both export and non-export establishments. Internal review visits were both announced and not announced in advance, and were conducted, at times, by individuals, and at other times by a team of reviewers, at least once monthly. The records of audited establishments were kept in the inspection offices of the individual establishments and at the office of the Director, Control of Animal Products in Tel Aviv.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export before it may again qualify for eligibility to be reinstated, a commission is empowered to conduct an in-depth review, and the results are reported to Dr. Oded Nir (Markusfeld), Director of Veterinary Services and Animal Health, for evaluation.

Enforcement Activities

Controls were in place to ensure adequate export product identification, inspector verification, export certificates, a single standard of control throughout the establishments, inspection supervision as required, and adequate controls for security items, shipment security, species verification, and products entering the establishments from outside sources.

Exit Meetings

An exit meeting was conducted in Beit Dagan on May 17, 2000. The Israel's participants were Dr. Oded Nir (Markusfeld), Director of Veterinary Services and Animal Health (VSAH); Dr. Isaac Klinger, Deputy Director, Veterinary Services and Animal Health; Dr. Eliezer Nili, Director, Control of Animal Products; Dr. Karol Vigvari, Area Supervisor, Northern District; and Dr. Roint Davidovitch, HACCP Project Manager; Mr. Tully Friedgut, Agricultural Specialist, American Embassy in Tel Aviv and Dr. Faizur Choudry, International Audit Staff Officer. The individual audit findings, as enumerated in the body of this report, were discussed.

The following deficiencies were discussed in detail:

1. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed. Neither establishment personnel nor GOI inspection officials were performing adequate ongoing verification activities of the HACCP program.

2. The zero-tolerance policy for visible fecal material on carcass was not enforced by the GOI inspection officials and establishment personnel, in Establishments 3, 5, 9, and 19 observed on-site audit and Establishments 11, 14, and 18, on records audit.

3. Both establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of all documentation pertaining to the monitoring of critical limits and, if appropriate, documentation that corrective actions were taken, including the proper disposition of the product, for each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail; GOI meat inspection officials indicated to implement this requirement promptly.

4. The intralaboratory check samples program was not adequately maintained: no check samples for chlorinated hydrocarbons and organophosphates were carried out in March or April 2000, and no check samples at all were being done for hormones, trace elements, chloramphenicol, sulfonamides, or antibiotics as required. This is a repeat deficiency from last audit.

5. Because of gross product contamination and lack of a single standard for pre-operational and operational SSOPs/equivalent programs and procedures and inadequate control over pest control programs, the sanitation status of Establishment 5 is not equivalent to that required in the U.S. program. Government of Israel (GOI) inspection service removed this establishment from the list of establishments eligible to export poultry and poultry products to the United States, effective May 16, 2000. The VSAH inspection officials stated that they would not certify this establishment until all the deficiencies corrected.

Israeli officials agreed to take the necessary steps to ensure that corrective actions and preventive measures, as promised during the audits and exit meetings in the individual establishments, would be implemented.

CONCLUSION

Eight establishments were audited: five were acceptable, two were evaluated as acceptable/re-review, and one was unacceptable. The deficiencies encountered during the on-site establishment audits, in those establishments which were found to be acceptable, were adequately addressed to the auditor's satisfaction. The VSAH inspection officials

reinforced the assurances made by field personnel during and at the conclusions of the on-site audits of the establishments, and stated that they would ensure prompt compliance.

The major concerns were the following:

1. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed. Neither establishment personnel nor GOI inspection officials were performing adequate ongoing verification activities of the HACCP program.

2. The zero-tolerance policy for visible fecal material on carcass was not enforced by the GOI inspection officials and establishment personnel, in Establishments 3, 5, 9, and 19 observed on-site audit and Establishments 11, 14, and 18 on records audit.

3. Both establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of all documentation pertaining to the monitoring of critical limits and, if appropriate, documentation that corrective actions were taken, including the proper disposition of the product, for each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail; GOI meat inspection officials indicated to implement this requirement promptly.

4. The intralaboratory check samples program was not adequately maintained: no check samples for chlorinated hydrocarbons and organophosphates were carried out in March or April 2000, and no check samples at all were being done for hormones, trace elements, chloramphenicol, sulfonamides, or antibiotics as required. This is a repeat deficiency from last audit.

5. Because of gross product contamination and lack of a single standard for pre-operational and operational SSOPs/equivalent programs and procedures and inadequate control over pest control programs, the sanitation status of Establishment 5 is not equivalent to that required in the U.S. program. Government of Israel (GOI) inspection service removed this establishment from the list of establishments eligible to export poultry and poultry products to the United States, effective May 16, 2000. The VSAH inspection officials stated that they would not certify this establishment until all the deficiencies corrected.

Dr. Faizur R. Choudry
International Audit Staff Officer

(signed) Dr. Faizur R. Choudry

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing.
D. Data collection instrument for *Salmonella* testing
E. Laboratory audit form
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
3	√	√	√	√	√	√	√	√
5	√	√	√	√	√	√	√1	√
9	√	√	√	√	√	√	√	√
19	√	√	√	√	√	√	√	√
52	√	√	√	√	√	√	√	√
104	√	√	√	√	√	√	√	√
108	√	√	√	√	√	√	√	√
186	√	√	√	√	√	√	√	√

1. The daily pre-operational and operational SSOPs records did not reflect the actual sanitary conditions observed in the establishment.

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
11	√	√	√	√	√	√	√	√
14	√	√	√	√	√	√	√	√
18	√	√	√	√	√	√	√	√
22	√	√	√	√	√	√	√	√
101	√	√	√	√	√	√	√	√
118	√	√	√	√	√	√	√	√
119	√	√	√	√	√	√	√	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. (except Est. 12, which was a cold-storage facility) was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. *The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.*
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis	3. All hazards identified	4. Use & users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. act's are described	9. Plan validated	10.Adequate verific. procedures	11.Adequate documentation	12. Dated and signed
3	√	√	√	√	√	√	√1	√2	√	√3	√	√
5	√	√	√	√	√	√	√1	√2	√	√3	√	√
9	√	√	√	√	√	√	√1	√2	√	√3	√	√
19	√	√	√	√	√	√	√1	√2	√	√3	√	√
52	√	√	√	√	√	√	√1	√2	√	√3	√	√
104	√	√	√	√	√	√	√1	√2	√	√3	√	√
108	√	√	√	√	√	√	√1	√2	√	√3	√	√
186	√	√	√	√	√	√	√1	√2	√	√3	√	√

1. The HACCP plan did not specify critical limits, monitoring procedures and monitoring frequencies performed for each CCP adequately.

2. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed.

3. Corrective actions to be followed in response to a deviation from a critical limit not addressed adequately in the written HACCP plan.

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	1. Flow diagram	2. Hazard analysis	3. All hazards identified	4. Use & users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. act's are described	9. Plan validated	10.Adequate verific. procedures	11.Adequate documentation	12. Dated and signed
11	√	√	√	√	√	√	√1	√2	√	√3	√	√
14	√	√	√	√	√	√	√1	√2	√	√3	√	√
18	√	√	√	√	√	√	√1	√2	√	√3	√	√
19	√	√	√	√	√	√	√1	√2	√	√3	√	√
22	√	√	√	√	√	√	√1	√2	√	√3	√	√
101	√	√	√	√	√	√	√1	√2	√	√3	√	√
118	√	√	√	√	√	√	√1	√2	√	√3	√	√
119	√	√	√	√	√	√	√1	√2	√	√3	√	√

1. The HACCP plan did not specify critical limits, monitoring procedures and monitoring frequencies performed for each CCP adequately.

2. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed.

3. Corrective actions to be followed in response to a deviation from a critical limit not addressed adequately in the written HACCP plan.

Attachment C

Data Collection Instrument for Generic *E. coli* Testing

Each establishment (except Est. 12, which was a cold-storage facility) was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

The results of these evaluations were as follows:

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6, Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
3	√	√	√	√	√	√	√	√	√	√
5	√	√	√	√	√	√	√	√	√	√
9	√	√	√	√	√	√	√	√	√	√
19	√	√	√	√	√	√	√	√	√	√

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

The results of these evaluations were as follows:

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6, Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
11	√	√	√	√	√	√	√	√	√	√
14	√	√	√	√	√	√	√	√	√	√
18	√	√	√	√	√	√	√	√	√	√

Attachment D

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
3	√	√	N/A	√	√	√
5	√	√	N/A	√	√	√
9	√	√	N/A	√	√	√
19	√	√	N/A	√	√	√
52	√	N/A	√1&2	√	√	√
104	√	N/A	√1	√	√	√
108	√	N/A	√1	√	√	√
186	√	N/A	√1	√	√	√

1. One Salmonella sample from ready to eat product from each shipment to be exported.
2. One Salmonella sample from raw ground product per week.
3. One Salmonella sample from raw ground product from each batch.

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
11	√	√	N/A	√	√	√
14	√	√	N/A	√	√	√
18	√	√	N/A	√	√	√
22	√	N/A	√1&3	√	√	√
101	√	N/A	√1	√	√	√
118	√	N/A	√1	√	√	√
119	√	N/A	√1&2	√	√	√